UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE WELLBUTRIN SR/ZYBAN ANTITRUST LITIGATION	Master File No. 02-CV-4398
THIS DOCUMENT RELATES TO:	Judge Bruce W. Kauffman
ALL ACTIONS	ORAL ARGUMENT REQUESTED

DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO DISMISS

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I. INTRODUCTION

The Complaint alleges in conclusory fashion that GlaxoSmithKline ("GSK")[1] has brought patent infringement suits "which are objectively baseless and without merit for the purpose of triggering the 30-month stay [of FDA approval of generic products] and extending the time during which [GSK] enjoy[s] complete exclusivity in the domestic market for Wellbutrin SR and Zyban." Compl. ¶ 6. Plaintiffs allege that this has "allowed Defendants to stymie generic competition," id., and that as a result, indirect purchasers of the products[2] have paid more for the drugs than they would have paid had generic products been available. Compl. ¶ 8.

Plaintiffs' conclusory allegations are deficient as a matter of law and are contradicted by facts in the Complaint and the public record. A close reading of the Complaint itself shows that the reason that no generic versions of Wellbutrin® SR or Zyban® are available on the market has everything to do with the failure of generic firms to qualify for the necessary regulatory approvals and nothing to do with litigation that GSK has brought. Andrx, the first company to file for approval by the Food and Drug Administration ("FDA") for generic versions of Wellbutrin SR and Zyban, has failed to secure FDA approval. This failure has nothing to do with GSK's patent suit, because the statutory thirty-month stay of FDA approval pending patent infringement litigation expired more than ten months ago. Consequently, the pendency of the litigation does not

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[1] The Complaint also names GSK's parent entity, GlaxoSmithKline PLC, Compl. ¶ 20, although it alleges no separate conduct on its behalf.

[2] The alleged class consists of "[a]ll persons and entities in the United States who, at any time from September 15, 1999 until present indirectly purchased Wellbutrin SR and/or Zyban in the United States other than for re-sale." Compl. ¶ 24.

prevent FDA from approving Andrx's ANDA for marketing generic versions of Wellbutrin SR and Zyban. Furthermore, the generic applicants that filed after Andrx cannot secure FDA marketing approval because Andrx as the first filer will enjoy a statutory 180-day period of market exclusivity before the products of other companies may be finally approved. Accordingly, it is Andrx's failure to secure FDA approval and market its product that has prevented the other generic firms from coming to market. Because there is no causal connection between the challenged conduct (the patent infringement suits and the thirty month stay) and the alleged injury (the lack of generic entry), Plaintiffs' Complaint must be dismissed.

II. THE FACTS[3]

GSK invented, manufactures, and markets Wellbutrin, a pharmaceutical used to treat depression. Compl. ¶¶ 48-49. The active ingredient in Wellbutrin is bupropion hydrochloride. Id. GSK also invented a sustained release version of bupropion hydrochloride which it markets as Wellbutrin SR.[4] Compl. ¶ 53. The sustained release formulation of the drug enables users to treat depression with only two daily doses. Id.

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[3] The facts in this section are taken from the Complaint and from relevant statutory and administrative materials of which this Court may take judicial notice. In considering the motion to dismiss, the Court is not bound to only the factual allegations in the Complaint but may "properly look at public records." S. Cross Overseas Agencies v. Wah Kwong Shipping Group Ltd., 181 F.3d 410, 426 (3d Cir. 1999). For instance, a court may take judicial notice of "records and reports of administrative bodies." Hotel Employees & Rest. Employees Int'l Union v. Stadium Hotel Partner, L.P., Civ. A. No. 94-4451, 1994 WL 585707, at *2 (E.D. Pa. Sept. 26, 1994). The Court may also consider "publicly available records and transcripts from judicial proceedings in related or underlying cases." Township of S. Fayette v. Allegheny County Hous. Auth., 27 F. Supp. 2d 582, 594 (W.D. Pa. 1998) (internal quotes omitted). The Court "may take judicial notice of another court's opinion – not for the truth of the facts recited therein, but for the existence of the opinion." Wah Kwong Shipping Group, 181 F.3d at 426.

[4] Wellbutrin SR is also approved for smoking cessation and marketed under the name Zyban for this purpose. Compl. ¶ 2.

The United States Patent and Trademark Office has issued U.S. patent number 5,427,798 to GSK, entitled "[c]ontrolled sustained release tablets containing bupropion." Compl. ¶ 66.

Under the Federal Food, Drug, and Cosmetic Act ("FD&CA"), 21 U.S.C. § 301 et seq. (2000), approval by the FDA is required before a company may begin selling a new drug in the United States. Compl. ¶ 34. In certain circumstances, the FD&CA permits generic companies to obtain approval by filing an Abbreviated New Drug Application ("ANDA"), which does not require the expensive safety and efficacy studies required of pioneer companies. Compl. ¶ 44. The ANDA must still, however, show that the generic product is bioequivalent to the approved innovative product and that the generic product will be subject to adequate manufacturing and quality controls.[5] If an ANDA applicant does not meet each and every one of the criteria set forth in FDA regulations, FDA must "refuse" approval of the ANDA. 21 C.F.R. § 314.127 (2002).

The Hatch-Waxman amendments to the FD&CA establish a process where resolution of patent disputes between an innovator company and a would-be generic

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[5] Specifically, an ANDA must include information to show that (1) the conditions of use prescribed, recommended, or suggested in the labeling proposed for the generic drug have been previously approved in a New Drug Application ("NDA") for the branded drug, (2) the active ingredient(s) in the generic drug are the same as in the branded drug, (3) the route of administration, dosage form, and strength are the same as in the branded drug, (4) the generic drug is bioequivalent to the branded drug, and (5) the labeling proposed for the new drug is the same as the branded drug. See 21 U.S.C. §§ 355(j)(2)(A)(i)-(v) (2000). In addition, an ANDA must show all of the same information required of NDAs (with the exception of safety and efficacy studies), including (1) a full list of the materials used as components of the generic drug, (2) a full statement of the composition of the generic drug, (3) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug, (4) samples of the generic drug and its components as requested, and (5) specimens of the proposed labeling of the generic drug. See 21 U.S.C. §§ 355(j)(2)(A)(vi) and 355(b)(1)(B)-(F) (2000).

entrant can take place while FDA conducts its substantive review of an ANDA. The Act requires innovator companies to list applicable patents in an FDA publication known as the Orange Book, and an ANDA filer must state its position vis-à-vis the listed patents. If the generic company seeks to market its product before any of the listed patents expire, the generic company must assert that those patents are invalid and/or that the generic product does not infringe ("a Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000). The Hatch-Waxman amendments provide that the generic company must give notice of this certification to the innovator company and that the filing of an ANDA in such circumstances constitutes an act of patent infringement. Compl. ¶ 45; 35 U.S.C. §§ 271(e)(2)(A), 355(j)(2)(B) (2000). This permits the innovator company to sue the generic company for patent infringement and seek resolution of the dispute while the generic company's application is proceeding through the FDA review process.

If the patent owner files a patent infringement suit against the ANDA applicant within forty-five days of receipt of the Paragraph IV certification notice, then FDA final approval of the generic drug "is automatically postponed until the earliest of: (i) the expiration of the patent; (ii) thirty months from the patent holders' receipt of the Paragraph IV certification (30-month stay); or (iii) a final judicial determination of invalidity or non-infringement from which no appeal can be or has been taken." Compl. ¶ 46 (citing 21 U.S.C. § 355(j)(5)(B)(iii) (2000) and 21 C.F.R. § 314.107 (2002)).

Five companies have filed ANDAs seeking FDA approval to market generic versions of Wellbutrin SR: Andrx, Watson, Impax, Eon, and Excel. Compl. ¶ 71. Andrx was the first to submit an ANDA to FDA, including a Paragraph IV certification, in

August 1999. Compl. ¶¶ 75-76. Watson's ANDA followed, and GSK received its Paragraph IV certification notice on or about October 26, 1999. Compl. ¶ 115. Impax, Eon and Excel all filed subsequent ANDAs with Paragraph IV certifications. Compl. ¶¶ 80, 81, 84-88. GSK filed patent infringement suits against these companies, although the case against Watson has settled. Compl. ¶¶ 94, 99, 105, 110, 116.

Plaintiffs do not allege that any of these five companies has received FDA approval to market the drug. The FDA can and does review ANDAs during the pendency of patent litigation and can grant an ANDA tentative approval while patent litigation is pending. 21 C.F.R. §§ 314.105, 314.125, 314.127 (2002). This is exactly what happened in this case; as Plaintiffs note, one company, Eon, has a tentative approval. Compl. ¶ 83. The Court may take judicial notice of the absence of any such final approval based on FDA's Center for Drug Evaluation and Research Listing of New & Generic Drug Approvals, http://www.fda.gov/cder/approval/b.htm (visited on Dec. 5, 2002) (attached as Ex. 1). Thus, under the FD&CA, the would-be generic entrants are not permitted to sell their products in the United States because of their failure to obtain FDA approval. Selling without approval would subject the products to seizure and could subject the executives involved to indictment and imprisonment. 21 U.S.C. §§ 333, 334 (2000).

The Complaint implies that the reason no generics are approved is the pending patent infringement actions, which by statute stayed the ability of FDA to approve ANDAs for generic versions of Wellbutrin SR or Zyban for the shorter of thirty months or the resolution of the patent suit. Compl. ¶ 6. The implication is not correct. The

thirty-month stay expired long ago in the case of Andrx.[6] As to the other ANDA filers, another provision of the FD&CA is pertinent. As the Complaint explains, the Hatch-Waxman amendments to the FD&CA provide an economic incentive to the manufacturer of the first generic drug to file an ANDA for a particular generic drug and challenge the listed patent(s) – i.e., "the first applicant to submit an ANDA with Paragraph IV Certification for a generic version of a brand-name drug receives a 180-day period of exclusivity before other ANDAs for the same drug can be approved by the FDA." Compl. ¶ 47. "The 180-day exclusivity period begins when the first ANDA applicant (a) either begins selling the generic drug or (b) obtains a final judgment of non-infringement in a patent infringement action, whichever occurs first. Thus, the first generic ANDA applicant has the opportunity to compete directly with the brand-name manufacturer for 180 days without competition from other generic manufacturers." Id.

Given that the first filer cannot engage in its first commercial sale absent FDA approval, a failure by the first firm to obtain FDA approval can delay approval for all other ANDA filers for that product, even if those later filers have satisfied FDA's approval requirements. That is what has happened here: the failure of Andrx, the first

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[6] The thirty months begins to run from the date the NDA holder receives notice from the ANDA applicant of its Paragraph IV certification, which of course predates any suit. See Compl. ¶ 46; 21 U.S.C. § 355(j)(5)(B)(iii) (2000). GSK received Andrx's Paragraph IV certification notice in August 1999. Compl. ¶¶ 75-76. The thirty-month stay as to Andrx therefore expired in February 2002. Plaintiffs may claim in reply, as they did in their Preliminary Statement of the Case filed on November 25, 2002, that "Glaxo has appealed the [Andrx] decision, allowing the 30 month statutory ban to stay active." This assertion is simply incorrect. Andrx's thirty-month stay is not affected by any decision whether to appeal or not to appeal. The stay has run its course in the Andrx case, and no action in the pending appeal can restart the thirty-month clock.

ANDA filer for generic Wellbutrin SR, to obtain FDA approval has prevented all other ANDA filers from receiving final FDA approval to sell their products.

Even if, as Plaintiffs allege, GSK had "instituted a series of patent infringement actions (and ha[d] aggressively prosecuted these actions) which are objectively baseless and without merit for the purpose of triggering the 30-month stay," Compl. ¶ 6, such an action had no effect because none of the generic firms has been able, within those thirty months, to obtain FDA approval. Andrx, which filed its ANDA over three years ago, is not barred from selling its product by the thirty-month stay, because that stay ended in February 2002. See 21 U.S.C. § 355(j)(5)(B)(iii); Compl. ¶¶ 75-76. But Andrx has yet to obtain the necessary FDA approval. And Eon, the one company that, as the Complaint correctly notes, has obtained tentative FDA approval, Compl. ¶ 83, cannot obtain final FDA approval until Andrx's 180 days of exclusivity has run.

III. ARGUMENT

A Rule 12(b)(6) motion requires a court to accept only "well-pleaded factual allegations" in a plaintiff's complaint as true. Beverly Enters., Inc. v. Trump, 182 F.3d 183, 186 (3d Cir. 1999), cert. denied, 528 U.S. 1078 (2000). The Court can and should disregard the Complaint's "bald assertions" or "legal conclusions" when deciding the motion to dismiss. Morse v. Lower Merion Sch. Dist., 132 F.3d 902, 906 (3d Cir. 1997); In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1429 (3d Cir. 1997). Furthermore, "conclusory allegations or legal conclusions masquerading as factual allegations" are not to be credited. Bailey v. Reed, No. 00-3363, 2002 WL 276470, at *1 (3d Cir. Feb. 27, 2002) (quoting Morse, 132 F.3d at 906) (unpublished decision). The

Court may also consider public records, including records and reports of administrative bodies and records from related judicial proceedings. See cases cited supra note 3.

A. The Federal Claims Must Be Dismissed Because Plaintiffs Have Not Alleged a Causal Connection Between GSK's Actions and the Alleged Injury

To state a cause of action for injunctive relief under Section 16 of the Clayton Act, a plaintiff must allege that the claimed loss or threat of loss (here, nonavailability of generic Wellbutrin SR) proximately results or will result from the alleged violation (here, sham patent litigation). See, e.g., McCarthy v. Recordex Serv., Inc., 80 F.3d 842, 856 (3d Cir. 1996); see also City of Pittsburgh v. West Penn Power Comp., 147 F.3d 256, 265 (3d Cir. 1998) (no injunction for antitrust violation where plaintiff could not show causal link between alleged violation and alleged harm).

Plaintiffs' allegations do not satisfy this requirement. The allegations and public record materials demonstrate that, even if GSK had never brought a single patent infringement case against any of the ANDA filers, no generic Wellbutrin SR would yet be available for purchase in the United States because none of the ANDA filers has received final FDA approval, for reasons entirely unrelated to GSK's patent infringement suits. To the extent purchasers of Wellbutrin SR have been injured because they did not have a generic equivalent available to them, the blame cannot be attributed to GSK.

1. In Actions Under Clayton Act Section 16, Plaintiffs Must Allege a Causal Connection Between the Defendants' Conduct and the Alleged Injury

It is hornbook antitrust law that "[t]o state a cause of action under Section 16 [of the Clayton Act], a plaintiff must allege that . . . [among other things], the loss or injury proximately results from the alleged antitrust violation." 1 ABA Section of Antitrust

Law, Antitrust Law Developments 868 (5th ed. 2002). In this context, Plaintiffs must plead that the generic manufacturers were prepared to enter the market but for the patent infringement suits filed by GSK. Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 807 (D.C. Cir. 2001), cert. denied, 122 S. Ct. 1305 (2002).

For instance, in Bristol-Myers Squibb Co. v. Copley Pharmaceutical, Inc., 144 F. Supp. 2d 21 (D. Mass. 2000), a generic drug seller, Copley, alleged that BMS's patent suit against it was a frivolous attempt to keep Copley off the market and maintain BMS's monopoly in violation of the antitrust laws. BMS responded that Copley had failed to show a causal link between BMS's conduct and the alleged harm. Id. at 22. The court agreed: "Because Copley has not received tentative FDA approval and because [the first ANDA filer's] 180-day period of market exclusivity has not run, Copley cannot show that [BMS's] lawsuit is preventing it from entering the market, and therefore, it fails to show antitrust injury." Id. at 25. The court therefore granted BMS's 12(b)(6) motion to dismiss Copley's antitrust counterclaim. Id.

The court in Andrx Pharms., Inc. v. Friedman, 83 F. Supp. 2d 179, 185-86 (D.D.C. 2000), aff'd in part, rev'd in part on other grounds, 256 F.3d 799 (D.C. Cir. 2001), cert. denied, 122 S. Ct. 1305 (2002), reached the same result, holding that an allegedly "delayed" would-be generic entrant could not sue for antitrust violations for its delayed entry when it had not shown that it had received FDA approval. The harm did not flow from the other party's conduct because "[t]he reason [the allegedly delayed entrant] cannot enter the market is because of the existence of a troublesome statutory scheme that prohibits it from marketing a drug until the first ANDA recipient goes to market, and which places no restrictions on when, or even whether, that applicant must

go to market." Id. at 185; see also Eli Lilly & Co. v. Zenith Goldline Pharms., Inc., 172 F. Supp. 2d 1060, 1078-79 (S.D. Ind. 2001) (no causal connection between generic seller's inability to enter market and alleged conduct where generic seller did not show that alleged conduct caused the FDA to fail to approve the generic seller's product).

2. Plaintiffs Have Not Alleged a Causal Connection Between the Filing of the Patent Infringement Lawsuits and the Lack of Generic Wellbutrin SR

The facts as contained in the Complaint and public records demonstrate that none of the would-be generic sellers of Wellbutrin SR is able to enter the market today for reasons that have nothing to do with GSK's patent infringement suits. Today, nearly three and a half years after filing its ANDA, Andrx has not received even tentative approval for its product, as evidenced by reviewing the FDA's listing of new drug approvals. See Ex. 1. As soon as Andrx is able to convince FDA that its product meets the statutory requirements for a new drug, it will be able to enter the market, because the Hatch-Waxman thirty-month stay expired long ago. GSK's lawsuit against Andrx therefore has not caused any injury to Plaintiffs.

That GSK's patent suit against Andrx did not delay entry is consistent with what the Federal Trade Commission recently concluded to be typical of such suits: "it does not appear that the 30-month stay provision, as applied once to each ANDA . . . has a significant potential to delay generic entry." Generic Drug Entry Prior to Patent Expiration: An FTC Study, Executive Summary, at iv (July 30, 2002), available at www.ftc.gov/OS/2002/07/genericdrugstudy.pdf. That is because "[o]n average, the time required for FDA review and approval was 25 months and 15 days from the application filing date in those cases where generic applicants filing a paragraph IV certification were

not sued (and thus could begin commercial marketing once they had FDA approval). On average, the time between the filing of a patent infringement lawsuit and a district court decision in the case was 25 months and 13 days." Id. at iii. Thus, the FTC has not recommended any change in the thirty-month stay provision as applied once to each ANDA as in this case.[7] Id.

GSK's patent infringement suits against the other four generic companies likewise have caused Plaintiffs no injury. Three of those companies, like Andrx, have not yet earned FDA approval. And the one company that has received tentative FDA approval, Eon, is not able to sell its product because Andrx's 180-day exclusivity period as the first ANDA filer has not run.

Plaintiffs therefore have not pled and cannot plead that any generic manufacturer is prepared to enter the market. Consequently, Plaintiffs cannot fairly plead that GSK's patent infringement litigations have delayed generic entry. Plaintiffs may have a beef with Andrx (the first filer that has been unable to satisfy FDA's requirements), the FDA, or Messrs. Hatch and Waxman, but Plaintiffs cannot state a claim against GSK.

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[7] President Bush recently agreed with the FTC that thirty months "is an appropriate time period for courts to resolve cases of patent infringement." Press Release, Office of the Press Secretary, President Takes Action to Lower Prescription Drug Prices By Improving Access to Generic Drugs (Oct. 21, 2002) available at www.whitehouse.gov/news/releases/2002/10/20021021-4.html (attached as Ex. 2).

B. The State Claims Must Also Be Dismissed Because of the Failure To Allege Any Causal Connection Between the Infringement Lawsuits and the Alleged Injury

Causation is as essential a pleading requirement under Plaintiffs' state antitrust and consumer protection law claims as it is under federal law.[8] Accordingly, those claims must be dismissed as well.

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[8] Alaska Stat. § 45.50.531 (1998); Ariz. Rev. Stat. §§ 44-1408, 44-1533 (1994); e.g., Sellinger v. Freeway Mobile Home Sales, Inc., 521 P.2d 1119, 1122 (Ariz. 1974) (holding that Ariz. Rev. Stat. § 44-1533 requires a causal connection between the loss or injury and the alleged violation); Ark. Code Ann. § 4-88-113 (1999); Cal. Bus. & Prof. Code § 16750 (1997) (Plaintiffs also cite to Cal. Bus. & Prof. Code §§ 17200, et seq. which does not allow a private cause of action); Colo. Rev. Stat. § 6-1-113 (2002); Conn. Gen. Stat. § 42-110g (1992); Del. Code Ann. tit. 6, § 2513 (1998) (held unconstitutional in part by Brady v. Preferred Florist Network, Inc., 791 A.2d 8, 18 (Del. 2001) finding that § 2513(a)(1) was unconstitutional; however that subsection is inapplicable here); see also e.g., Young v. Joyce, 351 A.2d 857, 859 (Del. 1975) (holding that Del. Code Ann. tit. 6, § 2513 requires a causal connection between the loss or injury and the alleged violation); D.C. Code Ann. § 28-4508 (2001) (Plaintiffs cite to D.C. Code Ann. §§ 28-45031, et seq. but there are no such statutes. Plaintiffs also cite D.C. Code Ann. §§ 28-3901, et seq. but these statutes do not allow a private right of action and have to do with only the consumer protection agency); Fla. Stat. ch. 501.211 (2002); Ga. Code Ann. § 10-1-399 (2000); Haw. Rev. Stat. § 480-13 (2001), amended by 2002 Haw. Laws Act 229 (S.B. 1320); Idaho Code § 48-608 (1990); 815 Ill. Comp. Stat. 505/10a (1999) (held unconstitutional in part by Allen v. Woodfield Chevrolet, Inc., 773 N.E.2d 1145, 1155 (Ill. Ct. App. 2002) finding the 1993 and 1996 amendments applicable only to car dealers unconstitutional; however those amendments do not apply here); Iowa Code Ann. § 553.12 (1997); Kan. Stat. Ann. §§ 50-115, 50-634 (1994); Ky. Rev. Stat. Ann. § 367.220 (2002); La. Rev. Stat. Ann. §§ 51:137, 51:1409 (1987); Me. Rev. Stat. Ann. tit. 5, § 213 (2002), tit. 10, § 1104 (1996); Md. Code. Ann., Com. Law § 13-408 (2002); Mass. Gen. Laws Ann. ch. 93, § 12, ch. 93A, §9 (1997); Mich. Comp. Laws Ann. §§ 445.778, 445.911 (2002); Minn. Stat. Ann. §§ 8.31 (1997), § 325D.57 (1995); Miss. Code. Ann. § 75-21-9 (2002); Mo. Rev. Stat. § 407.025 (2001); Mont. Code Ann. § 30-14-133 (2002); Neb. Rev. Stat. §§ 59-821, 59-1609 (2002); Nev. Rev. Stat. Ann. 598.0977 (1993), 598A.210 (1999); N.H. Rev. Stat. Ann. § 358-A:10 (1994); N.J. Stat. Ann. § 56:8-19 (2001); N.M. Stat. Ann. §§ 57-1-3, 57-12-10 (1978); N.Y. Gen. Bus. Law §§ 340, 349 (1988); N.C. Gen. Stat. § 75-16 (2002); N.D. Cent. Code § 51-08.1-08 (2001) (Plaintiffs also cite to N.D. Cent. Code §§ 51-15-01, et seq. but these statutes do not allow a private right of action. See e.g., Ziegelmann v. DaimerChrysler Corp., 649 N.W.2d 556, 559 (N.D. 2002)); Ohio Rev. Code Ann. § 1345.09 (2002); Okla. Stat. tit. 15, § 761.1 (1993); Or. Rev. Stat. § 646.638 (2001); 73 Pa. Cons. Stat. § 201-9.2 (1993); R.I. Gen. Laws § 6-13.1-5.2 (2001); S.C. Code Ann. § 39-5-140 (1976); S.D. Codified Laws §§ 37-1-14.3 (1977), 37-24-31 (1971); Tenn. Code Ann. §§ 47-18-109 (1991), 47-25-106 (2002); Tex. Bus. & Com. Code Ann. § 17.50 (2002); Utah Code Ann. § 13-11-19 (1995); Vt. Stat. Ann. tit. 9, § 2465 (1999); Va. Code Ann. § 59.1.204 (1995); Wash. Rev. Code § 19.86.090 (1999); W. Va. Code §§ 46A-6-106 (1974), 47-18-9 (1978); Wis. Stat. Ann. § 133.18 (2001).

Similarly, Plaintiffs' claim of unjust enrichment fails because no "unjust" enrichment exists if defendant did not cause the alleged injury. GSK enjoyed lawful profits and was not unjustly enriched, because its actions did not restrict generic entry. See, e.g., Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc., 171 F.3d 912, 921 (3d Cir. 1999), cert. denied, 528 U.S. 1105 (2000) (holding "[w]e can find no justification for permitting plaintiffs to proceed on their unjust enrichment claim once we have determined that the District Court properly dismissed the traditional tort claims because of the remoteness of plaintiffs' injuries from defendants' wrongdoing").[9]

Thus, for the same reasons Plaintiffs' federal claim should be dismissed, Plaintiffs' state claims should be dismissed as well.[10]

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[9] See also Allegheny Gen. Hosp. v. Philip Morris, Inc., 116 F. Supp. 2d 610, 621 (W.D. Pa. 1999), aff'd, 228 F.3d 429 (3d Cir. 2000) (following Steamfitters and agreeing that it would be "improper to allow Plaintiffs to proceed with their restitution/unjust enrichment claim against Defendants having determined that their traditional tort claims must be dismissed because of the remoteness of the Plaintiffs' alleged injuries from the Defendants' alleged conduct"); Solomon v. Guardian Life Ins. Co. of Am., No. CIV.A. 96-1597, 1996 WL 741888, at *2 (E.D. Pa. Dec. 10, 1996) (dismissing plaintiff's unjust enrichment cause along with other tort claims, including a consumer protection claim because plaintiff failed to adequately plead damages and holding "[a]lthough a claim for unjust enrichment does not expressly require the element of damages or injury suffered by plaintiff, the amount by which a defendant [is] enriched will be equated to the amount of damages incurred by plaintiff for purpose of this Court's analysis"); see, e.g., Renkiewicz v. Commercial Union Life Ins. Co. of Am., No. CIV.A. 98-CV-1564, 1999 WL 820452, at *3 (E.D. Pa. Sept. 29, 1999) (agreeing with Solomon and holding that this case is analytically identical to Solomon in that unjust enrichment claim must be dismissed because no injury can be demonstrated).

[10] Furthermore, Plaintiffs have ignored jurisdictional state requirements. For example, Plaintiffs have disregarded state laws that require a consumer to mail or deliver a written demand for relief prior to filing a private consumer suit. See, e.g., Me. Rev. Stat. Ann. tit. 5, § 213 (2002); Mass. Gen. Laws Ann. ch. 93A, § 9 (1997). Plaintiffs have either failed to send any written demand or have sent an inappropriate demand. In the event that Plaintiffs' Complaint is not dismissed according to this Memorandum in Support of Motion to Dismiss, Defendants reserve the right to move to dismiss Plaintiffs' state law claims based on jurisdictional deficiencies.

IV. CONCLUSION

For the reasons stated herein, Plaintiffs' Complaint should be dismissed.

Respectfully submitted,

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Dated: December 5, 2002

EXHIBIT 1

Bleomycin for Injection USP, 15 units base/vial & 30 units base/vial, Rx	Gensia Sicor Pharmaceuticals, Inc.	ANDA 65-033	6/27/00	10/30/00		
Bleomycin for Injection USP, 15 units base/vial & 30 units base/vial, Rx	Faulding Pharmaceutical Co.	ANDA 65-031	3/10/00	3/15/00		
Blocadren (Timolol Maleate) Tablets,	Merck & Co., Inc.	NDA 18-017/S-037	3/27/02	4/8/02		5/30/02
Bravelle (Urofollitropin) Injection Purified, Rx	Ferring Pharmaceuticals, Inc.	NDA 21-289	5/6/02	5/9/02		10/9/02
	Bravelle Indication: Ovulation Induction					
Brevibloc (Esmolol Hydrochloride) Injection, 250 mg/mL Ampule & 10 mg/mL Vial, Rx	Baxter Pharmaceutical Products Inc.	NDA 19-386	1/19/00			6/4/01
Brevital Sodium (Methohexytal sodium for injection USP), Rx	Eli Lilly and Company	NDA 11-559/S-032	7/13/01	10/10/02		
Bromocriptine Mesylate Capsules USP, 5 mg (base)	Lek USA, Inc.	ANDA 75-100	12/10/98	12/10/98		8/24/01
Bumex (bumetanide) Tablets & Bumex (bumetanide) Injection, 0.25, 1 and 2 mg & 0.25 mg/mL, respectively, Rx	Hoffmann-La Roche Inc.	NDA 18-225/S-018 & 019 & 18-226/S-024 & 025	10/29/02	11/19/02		
Bupivacaine HCI Injection USP, 0.25%, 0.50% & 0.75%, Rx	International Medication Systems, Limited	ANDA 76-012	1/9/02			
Buprenex (buprenorphine hydrochloride) Injectable,	Reckitt Benckiser Pharmaceuticals, Inc.	NDA 18-401/S-014	2/11/02	3/8/02		
Bupropion Hydrochloride Extended-Release Tablets, 100 and 150 mg, Rx	Eon Labs Manufacturing, Inc.	ANDA 75-932	1/24/02			
Bupropion Hydrochloride Tablets, 75 mg and 100 mg, Rx	Eon Labs Manufacturing, Inc.	ANDA 75-613	10/10/00	11/7/00		12/5/01
Bupropion Hydrochloride Tablets, 75 mg and 100 mg, Rx	Invamed Inc.	ANDA 75-584	2/7/00	2/11/00		6/7/01
Bupropion Hydrochloride Tablets, 75 mg and 100 mg, Rx	Mylan Pharmaceuticals Inc.	ANDA 75-491	4/17/00	4/24/00		
BuSpar (Buspirone	Bristol-Myers	NDA 18-	2/7/02	4/17/02		

EXHIBIT 2

the White House
President George W. Bush

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For Immediate Release
Office of the Press Secretary
October 21, 2002

President Takes Action to Lower Prescription Drug Prices By Improving Access to Generic Drugs

TODAYS PRESIDENTIAL ACTION

- President Bush announced a new rule to lower prescription drug costs for millions of Americans by improving access to generic drugs, which are safe and effective and can be much less costly alternatives to brand-name prescription drugs. The proposed rule is expected to lead to savings in drug costs of over **$3 billion per year** for Americas consumers.

- This regulatory action will close loopholes in the implementation of the Hatch-Waxman law, which governs how generic drugs can compete with brand-name drugs. As a result, patients will benefit from greater and more predictable access to safe, effective, low-cost generic alternatives to brand-name drugs.

DETAILS OF FDAS PROPOSED RULE ON GENERIC DRUGS

The new FDA rule will:

- **Implement Federal Trade Commission (FTC) recommendations** for improving access to generic drugs by making significant changes in the use of automatic 30-month stays and in the drug patent listing process.

- **Allow one 30-month automatic stay at most in patent infringement litigation involving a generic drug application**: Drug manufacturers would be limited to only one 30-month stay per generic application, to resolve allegations that a generic drug maker is infringing a drug patent. According to the FTC, this is an appropriate time period for courts to resolve cases of patent infringement. Multiple 30-month stays, which have led to delays in generic entry of an additional 4 to 40 months, would not be permitted.

- **Tighten requirements and increase disclosures for drug patent listings**: Drug manufacturers would no longer be allowed to list patents in the FDA Orange Book for drug packaging, drug metabolites, and intermediate forms of a drug. Permitted listings include patents on active ingredients, drug formulations, and uses of a drug. In addition, a more detailed signed attestation accompanying a patent submission will be required, and false statements in the attestation can lead to criminal charges. This will significantly reduce opportunities to list inappropriate patents just to prevent fair competition from generic drugs.

- **Provide billions of dollars in savings for public and private health insurance programs**: The rule will not only provide savings for patients by giving them more safe and effective, low-cost prescription drug alternatives; it will reduce budgetary pressures on state Medicaid programs, and reduce the cost burdens facing employer-provided coverage.

- **Lower the cost of improving Medicare with prescription drug coverage**: The rule provides important relief for seniors, but it is only a first step. Seniors really need an improved and

strengthened Medicare program like the President has proposed, with better and more secure coverage options. While the House of Representatives took an important first step this year by passing legislation to provide drug coverage, the Senate failed to act. The President is calling on the leadership of the Senate to put politics aside and pass a prescription drug benefit for Medicare. The proposed rule makes this job easier by reducing the cost of a Medicare prescription drug benefit.

BACKGROUND ON TODAYS PRESIDENTIAL ACTION

Todays Presidential action improves the FDA regulations implementing the Hatch-Waxman law. These regulations govern when generic drugs can compete with brand-name drugs. As a result, patients will benefit from greater and more predictable access to effective, low-cost generic alternatives to brand-name drugs.

- Under the Hatch-Waxman law passed in 1984, generic competition is allowed when a new drugs patent and market exclusivity protection expires, or when a 30-month stay terminates. The intent of the law is to provide incentives to develop valuable new drug treatments through patent protection, but also to facilitate access to generic versions of the drug after the innovators patent expires.
- FDA-approved generic drugs are safe and effective alternatives to many brand-name prescription drugs, at a cost that is often only one-third as great. Almost half of all prescriptions filled today are for generic drugs, and generic alternatives exist for many commonly-used brand name medications providing an equally safe and effective but much less expensive alternative for millions of Americans.

- In recent years, however, access to generic drugs has sometimes been delayed by litigation. Under FDAs past interpretations of the Hatch-Waxman law and the Orange Book patent listing process, drug manufacturers have been able to file additional patents on packaging, ingredient combinations, and other minor matters in order to get repeated 30-month automatic stays in court that significantly delay access to generic drugs.

- In response to bipartisan Congressional concern about this issue, the FTC conducted a detailed study of Generic Drug Entry Prior to Patent Expiration. The study was issued in July 2002. It identified cases involving seven major brand-name drugs between 1994-2000 where the repeated use of automatic stays on late-filed patents had delayed access to generic drugs. The FTC made the following recommendations:

- Allow only one automatic stay per generic drug application; and
- Tighten the Orange Book patent listing process to help ensure that only appropriate patents are filed.

The proposed rule can be viewed at **www.fda.gov/ohrms/dockets**.

For more information on the Presidents initiatives please visit **www.whitehouse.gov**

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CERTIFICATE OF SERVICE

I certify that the foregoing Defendants' Memorandum in Support of Motion to Dismiss was served on the counsel listed in the service list below by fax and overnight mail on December 5, 2002.

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